

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TEXAS
SHERMAN DIVISION**

AMERICAN CLINICAL
LABORATORY ASSOCIATION;
HEALTHTRACKRX INDIANA,
INC.; and HEALTHTRACKRX,
INC.,

Plaintiffs,

v.

U.S. FOOD AND DRUG
ADMINISTRATION; U.S.
DEPARTMENT OF HEALTH AND
HUMAN SERVICES; XAVIER
BECERRA, in his official capacity as
Secretary of Health and Human
Services; and ROBERT M. CALIFF,
M.D., in his official capacity as
Commissioner of Food and Drugs,
United States Food and Drug
Administration,

Defendants.

Case No.: 4:24-cv-479

COMPLAINT

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COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiffs American Clinical Laboratory Association (“ACLA”) and HealthTrackRX Indiana, Inc. and HealthTrackRX, Inc. (together “HealthTrackRX”) bring this action against the Food & Drug Administration (“FDA”), the Department of Health and Human Services, and the Secretary of Health and Human Services and the FDA Commissioner in their official capacities, challenging the final rule published on May 6, 2024, announcing FDA’s intent to regulate laboratory-developed tests as medical devices under the Federal, Food, Drug and Cosmetic Act. Because the final rule exceeds FDA’s lawful authority and is arbitrary and capricious and contrary to law, the rule should be set aside and vacated, and defendants should be enjoined from enforcing or implementing the rule. *See* 5 U.S.C. § 706. Plaintiffs allege as follows:

PRELIMINARY STATEMENT

1. The professional diagnostic testing services provided by clinical laboratories are an essential part of the nation’s healthcare system. These important testing services have long been relied on by healthcare providers to diagnose and develop appropriate treatments for patients who suffer from illness and disease. There are thousands of laboratories across the United States that offer tens of thousands of molecular and other types of high-quality diagnostic testing services to providers and patients. These testing services are

a critical pillar of our nation’s health care system.

2. For decades, laboratory-developed testing services (often referred to as “LDTs”) have been regulated under a statutory and regulatory framework—the Clinical Laboratory Improvement Amendments Act of 1988 (“CLIA”)—that imposes numerous laboratory-specific standards to ensure the validity and reliability of laboratory diagnostic testing services, including the training and qualifications of the skilled professionals who perform, supervise, and interpret those tests. When creating and performing testing services, these laboratory professionals have not generally been required to comply also with the costly and burdensome pre-approval and clearance requirements that the Federal Food, Drug and Cosmetic Act (“FDCA”) authorizes FDA to apply to manufactured medical devices sold in interstate commerce. Nor has Congress ever granted FDA authority to regulate professional laboratory-developed testing services.

3. FDA’s final rule threatens to upend the nation’s entire laboratory profession by seeking to regulate all laboratory-developed tests as if they are medical devices under the FDCA. In asserting authority to transform the regulatory framework that has applied for decades, FDA cannot point to any new statutory authority granted by Congress. Nor can FDA contend that Congress has ever provided it with the resources that would be necessary to retain the personnel and build the expertise necessary to exercise sweeping

authority over the thousands of testing services provided by the nation's laboratories. To the contrary, Congress has recently entertained legislative proposals that would have granted FDA new authority to regulate laboratory-developed testing services, and it has declined to provide FDA that power.

4. FDA's final rule relies on the extraordinary position that in 1976, when Congress expanded FDA's authority to regulate medical devices, it also quietly intended to outlaw—and subject to substantial civil and criminal monetary penalties—any professional laboratory-developed testing services that were not first approved or cleared by FDA. The logic of FDA's position is that tens of thousands of professionals across the country performing millions of diagnostic testing services every year, working with thousands of doctors and patients, have for decades done so in open and direct violation of the law. According to FDA, the only reason laboratories have not been civilly and criminally punished is because FDA has chosen to exercise unreviewable “enforcement discretion.” In short, FDA is taking the position that a “long-extant statute” grants it vast, “transformative” regulatory powers that it has not previously exercised—a position that courts have rightly approached with deep skepticism. *West Virginia v. EPA*, 597 U.S. 697, 724 (2022) (quoting *Util. Air Regul. Grp. v. EPA*, 573 U.S. 302, 324 (2014)).

5. If it is not vacated, FDA's unprecedented final rule will have devastating and far-reaching consequences not only for the nation's clinical

laboratories, but also for the nation's entire healthcare system, including the millions of vulnerable patients who depend on the essential clinical testing services that laboratories provide. FDA's final rule means that, in order to be *legally* marketed, virtually all diagnostic laboratory tests will have to undergo costly and time-consuming administrative review through a regulatory process that was designed for evaluating manufactured medical devices, not professional testing services.

6. The final rule states that FDA intends to apply this onerous regulatory regime to new and modified laboratory-developed tests, which will dramatically increase research and development costs, hinder vital medical innovation, and hamper adaptation of existing tests to meet evolving patient needs. Indeed, FDA itself has recognized "significant regulatory changes" to the treatment of laboratory testing services "could have negative effects on the public health." 62 Fed. Reg. 62,243, 62,249 (Nov. 21, 1997). With respect to unmodified existing tests, FDA states that as a matter of enforcement discretion it generally does not intend—at least not at this time—to enforce certain especially burdensome medical-device requirements, such as premarket review. But FDA's final rule means that in the agency's view all of those tests, including tests that physicians have relied on for decades, are being marketed illegally and are subject to FDA enforcement action at any time.

7. FDA does not have authority to regulate professional laboratory-

developed testing services as medical devices. The text and structure of the FDCA make plain that FDA’s authority to regulate “devices,” which dates to 1938 and was expanded through the Medical Device Amendments of 1976, extends only to physical products that are sold and distributed by manufacturers in interstate commerce. The FDCA has never applied medical device regulation to laboratory testing services. And for good reason: Those tests are not physical products sold and distributed by manufacturers. Instead, they are professional healthcare services offered by highly skilled and trained laboratory professionals that are outside FDA’s regulatory expertise and are subject to different regulatory requirements. A laboratory-developed test is a process by which laboratory professionals use various tools—some of which may be individually regulated as devices—to derive diagnostic information that a patient and the patient’s physician may use in making health care decisions.

8. Nor has FDA provided any plausible interpretation of the statute that could support its approach. FDA’s assertion that laboratory testing services are devices just because the professionals performing those services *use* devices is as unreasonable as calling a surgical procedure a “device” because the surgeon uses a scalpel, or calling a doctor’s physical examination a “device” because the doctor uses a stethoscope. The fact that a skilled professional may use physical tools, in addition to his or her professional

expertise, training, and judgment, to perform a procedure does not mean that the procedure itself is a device.

9. Equally untenable is FDA's contention that laboratory testing services are devices because they serve a similar function to in vitro diagnostic test kits, which FDA regulates as devices. An IVD test kit is a "device" because it is a packaged set of components manufactured and sold in interstate commerce as a single physical product, like an at-home COVID test. Such commercial test kits are fundamentally different from laboratory-developed tests, which are professional services performed by professional clinicians in a laboratory.

10. As noted above, the development and performance of laboratory-developed tests is regulated at the federal level under a separate statutory and regulatory framework—CLIA—that ensures the validity and reliability of laboratory tests and the training and qualifications of the skilled professionals who perform, supervise, and interpret those tests. Notably, when Congress enacted CLIA, it did not so much as hint that it had already granted FDA authority to regulate laboratory testing services as medical devices under the FDCA. If Congress had wanted to expand FDA's authority so dramatically over an entire profession, it would have said so.

11. In its proposed rule, FDA initially contended that nearly all existing laboratory-developed tests would have to go through a burdensome

approval or clearance process before they could continue to be used to help patients and physicians. In the final rule, recognizing that its sweeping interpretation would be unworkable and have devastating consequences, FDA tried to rewrite the FDCA in the guise of dozens of pages of vague, non-binding “enforcement discretion policies” that are designed to mitigate (but not eliminate) those consequences. This “need to rewrite” the statute “should have alerted [FDA] that it had taken a wrong interpretive turn.” *Util. Air Regul. Grp.*, 573 U.S. at 328. “Agencies are not free to ‘adopt ... unreasonable interpretations of statutory provisions and then edit other statutory provisions to mitigate the unreasonableness.’” *Id.* (quotation marks omitted).

12. The final rule repeatedly warns that FDA may change its enforcement discretion policy at any time and bring the hammer down on laboratories for unlawfully marketing existing tests. Even if FDA never takes that step, the rule creates enormous regulatory uncertainty for laboratories and places them in an impossible position: They must either (1) withdraw all their existing tests from the market (which FDA recognized would be devastating for patients and the public health); (2) incur massive costs to obtain FDA approval or clearance for their existing tests, which would divert resources from innovating and developing new tests and overwhelm FDA; or (3) continue serving patients by providing existing tests without FDA approval or clearance, even though FDA says that by doing so they are breaking the law

and are subject to enforcement action at any time in the agency's sole discretion.

13. In addition to casting a shadow over all existing tests, the final rule undermines innovation and threatens patient access to critical new diagnostic tests. FDA lacks the expertise or resources to timely and efficiently review and approve new and modified laboratory-developed testing services. Moreover, given the need for FDA approval or clearance, the rule will discourage laboratories from devoting scarce resources to research and development, which will impede the creation of new and improved tests for cancer, infectious disease, cardiovascular disease, and countless other diseases and conditions. Because many tests do not generate sufficient revenue to support the expense of seeking FDA approval or clearance, many important tests will never be developed—especially tests for rare diseases or that serve small patient populations, such as children or racial or ethnic minorities.

14. FDA has identified no genuine public-health justification for imposing these costs on laboratories and the physicians and patients who rely on them. The agency's exercise of enforcement discretion for existing tests only underscores the lack of a valid public-health rationale for treating *any* laboratory-developed tests as medical devices.

15. For these reasons and those explained below, ACLA and HealthTrackRx seek declaratory and injunctive relief to vacate, set aside, and

enjoin enforcement of the final rule.

PARTIES

16. Plaintiff American Clinical Laboratory Association (“ACLA”) is a not-for-profit association with its principal place of business in Washington, D.C. ACLA is the national trade association representing leading laboratories that deliver essential diagnostic health information to patients and providers. ACLA’s members perform hundreds of millions of tests each year for patients across the country, and ACLA advocates for policies that expand access to the highest quality clinical laboratory services, improve patient outcomes, and advance the next generation of personalized care.

17. Plaintiff HealthTrackRx Indiana, Inc. is a corporation organized and existing under the laws of Indiana with its principal place of business in Denton, Texas. Plaintiff HealthTrackRX, Inc., is a corporation organized and existing under the laws of Texas with its principal place of business in Denton, Texas. HealthTrackRx is a leading national PCR-based infectious disease laboratory, providing services to over 10,000 clinicians nationwide. HealthTrackRx is also an ACLA member.

18. Defendant FDA, which has its principal office at 10903 New Hampshire Avenue, Silver Spring, Maryland 20993, is a federal agency headquartered in Maryland. It regulates drugs and medical devices under authority delegated by Congress and the Secretary of Health and Human

Services.

19. Defendant U.S. Department of Health and Human Services, which has its principal office at 200 Independence Avenue, S.W., Washington, D.C. 20201, is a federal agency headquartered in the District of Columbia. It has authority over FDA.

20. Defendant Xavier Becerra is being sued in his official capacity as Secretary of Health and Human Services. As Secretary, Mr. Becerra has ultimate responsibility for the activities of the Department of Health and Human Services, including those actions complained of herein. Mr. Becerra maintains an office at 200 Independence Avenue, S.W., Washington, D.C. 20201.

21. Defendant Robert Califf, M.D., is being sued in his official capacity as Commissioner of Food and Drugs, FDA. As Commissioner, Dr. Califf is responsible for the activities of FDA, including those actions complained of herein. Dr. Califf maintains an office at 10903 New Hampshire Avenue, Silver Spring, Maryland 20993.

JURISDICTION AND VENUE

22. This Court has original subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331 because it arises under the laws of the United States.

23. Plaintiffs have a right to bring this action pursuant to the

Administrative Procedure Act (“APA”), 5 U.S.C. §§ 701–706, and the Declaratory Judgment Act, 28 U.S.C. § 2201.

24. Plaintiffs have standing because they or their members provide thousands of laboratory-developed tests that would be treated as devices under the final rule, making them direct objects of regulation under that rule. *See* Dr. Reddy Decl. ¶¶ 6–7, 9–14, 24–37 (attached as Ex. A); Dr. Eisenberg Decl. ¶¶ 6, 8–10, 12, 18–20 (attached as Ex. B); Dr. Fesko Decl. ¶¶ 5–11 (attached as Ex. C); Dr. Genzen Decl. ¶¶ 12–13, 16–18, 22 (attached as Ex. D); Dr. Morice Decl. ¶¶ 19, 22, 25–30 (attached as Ex. E). Plaintiffs and their members also engage in research and development efforts to bring to market new and modified tests that would be treated as devices under the final rule. *See* Dr. Reddy Decl. ¶¶ 20, 24, 32, 36–37; Dr. Eisenberg Decl. ¶¶ 6, 8, 9–10, 12, 18–19; Dr. Fesko Decl. ¶¶ 7, 9, 16, 19–21; Dr. Genzen Decl. ¶¶ 19–21, 25–42, 47–50, 58–59; Dr. Morice Decl. ¶¶ 9, 17–18, 22–26, 58.

25. There is currently an actual, justiciable controversy between the parties concerning whether FDA’s final rule is consistent with the requirements of the FDCA, 21 U.S.C. § 301 *et seq.*, and the APA.

26. Venue is proper in this District pursuant to 28 U.S.C. § 1391(e) because this is a civil action in which the defendants are officers or agencies of the United States, plaintiff HealthTrackRx resides in this District, and no real property is involved in this action. *See* Dr. Reddy Decl. ¶ 8.

GENERAL ALLEGATIONS

A. Laboratory-developed tests are services carried out by highly skilled and trained laboratory professionals.

27. Laboratory-developed tests are procedures designed, developed, and performed by clinical laboratories certified to perform high-complexity testing to yield important clinical information about a patient that can be used to inform or guide patient care. *See* Dr. Reddy Decl. ¶¶ 9–17, 23; Dr. Eisenberg Decl. ¶¶ 6–10, 15; Dr. Fesko Decl. ¶¶ 5–11; Dr. Genzen Decl. ¶¶ 11–13, 15–20, 23–26, 28; Dr. Morice Decl. ¶¶ 14, 27–28, 48–52.

28. Laboratories that develop and perform these tests are providing professional healthcare services; they are not acting as device manufacturers or distributing devices. *See* Dr. Reddy Decl. ¶¶ 21–23; Dr. Eisenberg Decl. ¶¶ 14–15, 18; Dr. Fesko Decl. ¶¶ 14–15; Dr. Genzen Decl. ¶¶ 43–45; Dr. Morice Decl. ¶¶ 14, 48–56.

29. As an example, consider the steps associated with performing a mass spectrometry test offered by an ACLA member laboratory. Mass spectrometry is a chemical analysis technique with many uses, including helping manage hormonal disorders such as Cushing’s syndrome and measuring proteins with functions related to cancer and Alzheimer’s disease. After a physician orders the test, a blood specimen is obtained by a phlebotomist and sent to the laboratory. Laboratory staff then perform the

following tasks:

a. *Pre-analytical steps.* The laboratory receives the blood sample and enters it into the laboratory information system. Laboratory staff then complete pre-analytical steps in accordance with the relevant standard operating procedures. That may include centrifuging the sample or aliquoting the sample into a separate tube for testing.

b. *Analytical steps.* A laboratory scientist prepares reagents, standards, and quality control materials, and retrieves the patient sample for testing. The scientist pipettes the applicable samples and reagents into a 96-well plate and extracts the analytes of interest using an automated liquid handling instrument. The scientist then enters relevant information into the instrument software and loads samples onto the testing system, which includes an automated sampler, liquid chromatography instrumentation, and a high-resolution mass spectrometer. When testing is complete, the scientist reviews the test both qualitatively and quantitatively (*e.g.*, reviewing chromatography and signal-to-noise ratios), including reviewing quality control to ensure the results are within parameters for acceptable performance. The scientist then reviews the patient results, uses software to determine the concentration of the analyte(s) being measured, and enters the results into the laboratory information system.

c. *Post-analytical steps.* A second laboratory scientist or lead

scientist reviews the results to confirm they were accurately interpreted, quantitated, and entered into the laboratory information system. The reviewing scientist approves the results, sending them to the patient's electronic medical record. The ordering physician then reviews the laboratory result produced by the test and uses it to inform patient care decisions.

30. This is a laboratory-developed testing service: a series of processes and tasks undertaken by trained laboratory professionals using instruments and other tools to derive information that may be useful to a treating physician. Under any reasonable interpretation, these procedures and the exercise of judgment that they require constitute a professional service, not a manufactured device. *See* Dr. Reddy Decl. ¶¶ 14, 22–23; Dr. Fesko Decl. ¶¶ 15, 20; Dr. Eisenberg Decl. ¶¶ 8, 14–15, Dr. Genzen Decl. ¶¶ 43–45; Dr. Morice Decl. ¶¶ 14, 48–56.

31. Laboratory-developed tests are a vital part of the U.S. healthcare system and make significant contributions to patient care. They have often been responsible for scientific innovations and breakthroughs—for example, testing for the BRCA1/BRCA2 genetic mutations that indicate susceptibility to breast and ovarian cancer—that have become part of the standard of care (and in some cases, have been incorporated into FDA-cleared or approved IVD test kits). They also play a critical role in responding to public health threats from rare or emerging pathogens and new synthetic drugs, such as fentanyl analogs.

32. Many important diagnostic tests are available *only* as laboratory-developed testing services because no FDA-cleared or approved test kit exists for a particular disease, condition, or patient population. And even when an approved or cleared test kit is available, laboratory-developed tests often perform better and are preferred by physicians. Unlike medical devices, which must always take their approved form, laboratory-developed tests can be updated and customized (under the supervision of a CLIA-qualified laboratory director) to take account of the latest scientific developments and the needs of particular patients and clinicians. *See* Dr. Reddy Decl. ¶¶ 17, 36–37; Dr. Genzen Decl. ¶¶ 26–27.

B. FDA’s statutory authority to regulate medical devices does not extend to professional services.

33. The FDCA was originally enacted by Congress in 1938. It authorized FDA to regulate “foods,” “drugs,” “devices,” and “cosmetics,” all of which were physical *products* that were mass-manufactured and commercially distributed. *See* Federal Food, Drug, and Cosmetic Act of 1938, Pub. L. No. 75-717, § 201(h), 52 Stat. 1040, 1041 (“The term ‘device’ ... means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or (2) to affect the structure or any function of the body of man or other animals.”); *see also id.* §§ 201(f), (g),

(i), 52 Stat. at 1040–41 (defining “food,” “drug,” and “cosmetic,” respectively).

34. Congress greatly expanded FDA’s authority over devices in the Medical Device Amendments of 1976 (“MDA”), Pub. L. No. 94-295, 90 Stat. 539, which amended the FDCA to “impose[] a regime of detailed federal oversight” on medical devices. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316 (2008).

35. The FDCA’s Medical Device Amendments classify medical devices into three categories based on the level of risk they present. Class I devices are subject only to “general controls” such as labeling requirements. Class II devices are also subject to “special controls” such as performance standards and postmarket surveillance measures. Class III devices are subject to “a rigorous regime of premarket approval.” *Id.* at 316–17 (quotation marks omitted); *see* 21 U.S.C. § 360c(a)(1).

36. There are a few statutory exceptions to these general rules. Class III devices that were marketed before the statute’s effective date in 1976 were allowed to remain on the market unless and until FDA promulgates a regulation requiring the submission of premarket approval applications. *Riegel*, 55 U.S. at 316–17; *see* 21 U.S.C. §§ 360c(f)(1), 360e(b)(1). Moreover, a new Class III device need not go undergo full premarket approval if FDA finds that the new device is “substantially equivalent” to a grandfathered device. 21 U.S.C. § 360c(f)(1)(A).

37. While the three device categories differ by level of risk, they all

comprise tangible, physical products. For example, Class I devices include “elastic bandages and examination gloves,” Class II devices include “powered wheelchairs and surgical drapes,” and Class III devices include “replacement heart valves, implanted cerebella stimulators, and pacemaker pulse generators.” *Riegel*, 552 U.S. at 316–17.

38. The statutory definition of “device” makes clear that FDA’s regulatory jurisdiction under the FDCA is limited to physical products and does not encompass professional services. The statute provides:

The term “device” ... means an *instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory*, which is—

(A) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

(B) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

(C) intended to affect the structure or any function of the body of man or other animals, and

which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

21 U.S.C. § 321(h)(1) (emphasis added).

39. All of the terms used in the FDCA’s definition of “device”—

“instrument,” “apparatus,” “implement,” “machine,” “contrivance,” “implant,” and “in vitro reagent”—refer to tangible, physical objects. Moreover, the statute uses the term “article” as a catch-all to encompass all “devices,” and the plain meaning of “article” does not include intangible services. An “article” is a “particular material thing, esp. one belonging to a specified class; a commodity; an item of goods or property.” *Article*, Oxford English Dictionary (2023), <https://www.oed.com/search/dictionary/?scope=Entries&q=article>.

Consistent with this common definition, courts have consistently construed the term “article” to mean a “material thing” or a “tangible item.” *See, e.g., ClearCorrect Operating, LLC v. ITC*, 810 F.3d 1283, 1290–94 (Fed. Cir. 2015) (construing the term “articles” in the Tariff Act), *reh’g en banc denied*, 819 F.3d 1334 (Fed. Cir. 2016) (mem.).

40. Other provisions of the FDCA confirm that a “device” is a physical product, not a service. Several key provisions are triggered only when a device is shipped or received in interstate commerce, commercially distributed, or held for sale—actions that, in ordinary parlance, can be performed on a tangible article but not on an intangible professional service.

41. For example, section 510(k) of the FDCA requires a device manufacturer to file a premarket notification report with FDA at least 90 days before “the introduction or delivery for introduction into interstate commerce for commercial distribution of a device.” 21 U.S.C. § 360(k). “Commercial

distribution” is defined in an FDA regulation to mean “any distribution of a device intended for human use which is held or offered for sale.” 21 C.F.R. § 807.3(b). Similarly, section 301(k) prohibits various acts “with respect to” a device “if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded.” 21 U.S.C. § 331(k). None of these provisions can reasonably be applied to an intangible professional service performed within a laboratory.

42. Still other provisions of the FDCA discuss devices in ways that make sense only if applied to physical products. For example, an application for premarket approval for a device must include, among other things: (i) a description of “the components, ingredients, and properties” of the device; (ii) a description of the methods, facilities and controls used in “the manufacture, processing, and, when relevant, packing and installation” of the device; and (iii) “such samples of such device and of components thereof as the Secretary may reasonably require” or “information concerning the location of one or more such devices readily available for examination and testing.” 21 U.S.C. § 360e(c)(1)(B), (C), (E). Intangible professional services do not have components, ingredients, or properties; the services are not manufactured, processed, packed, or installed (even if providing them might entail using a manufactured product or products); and samples of a service cannot be

submitted to FDA or made readily available for inspection. *See* Dr. Reddy Decl. ¶¶ 22–23; Dr. Eisenberg Decl. ¶¶ 14–15; Dr. Fesko Decl. ¶ 15; Dr. Genzen Decl. ¶ 45; Dr. Morice Decl. ¶¶ 14, 48–56.

43. So too, the statute provides that in certain circumstances FDA may order the manufacturer, importer, or distributor of a device to “repair the device” or “replace the device with a like or equivalent device.” 21 U.S.C. § 360h(b). Unlike physical products, intangible professional services cannot be repaired or replaced.

44. Several of FDA’s promulgated regulations for devices can similarly be understood only as applied to a manufactured product. For example, an FDA regulation requires the “label of every medical device” and “[e]very device package” to bear a unique device identifier. 21 C.F.R. § 801.20(a). “Label” is defined as “a display of written, printed, or graphic matter upon the immediate container of any article,” and “device package” is defined as “a package that contains a fixed quantity of a particular version or model of a device.” *Id.* § 801.3 (incorporating 21 U.S.C. § 321(k)). These requirements make sense in the context of manufactured devices, where the primary and expected means of communication between the manufacturer and any purchaser is through a standardized label. In sharp contrast, a laboratory scientist’s performance of the tasks comprising a laboratory-developed test cannot be “labeled” or “packaged” in compliance with these regulations. Nor can those professional

services be summarized in a standardized label; instead, clinical laboratory services entail the exercise of professional judgment when interpreting testing results and often a consultation process between professional laboratory clinicians and doctors and other healthcare providers. *See* Dr. Eisenberg Decl. ¶ 14; Dr. Fesko Decl. ¶¶ 9, 15; Dr. Genzen Decl. ¶ 19; Dr. Morice Decl. ¶¶ 27, 48–56.

45. Viewed collectively, these provisions confirm what the statutory definition of “device” makes clear: A “device” under the FDCA is a physical product or manufactured good, not an intangible professional service.

C. Congress created a separate and distinct framework for regulating laboratory testing services.

46. Congress created a separate statutory and regulatory framework to regulate laboratory testing services: the Clinical Laboratories Improvement Act of 1967, Pub. L. No. 90-174, § 5, 81 Stat. 533, 536, which was significantly expanded by the Clinical Laboratory Improvement Amendments of 1988, Pub. L. No. 100-578, 102 Stat. 2903, codified at 42 U.S.C. § 263a. This statutory framework is commonly referred to as “CLIA.”

47. Congress’s enactment and expansion of CLIA in 1967 and 1988 confirms that it did not understand the Medical Device Amendments in 1976 as authorizing FDA to regulate laboratory testing services as medical devices.

48. CLIA establishes a framework for the regulation of laboratories

and laboratory testing services. Within the Department of Health and Human Services, responsibility for administering CLIA belongs primarily to the Centers for Medicare and Medicaid Services (“CMS”), which has issued extensive implementing regulations. *See generally* 42 C.F.R. Part 493.

49. CLIA and its implementing regulations reflect that performing and interpreting laboratory tests requires significant scientific and technical knowledge, training, experience, and judgment, and is fundamentally different from manufacturing physical devices. *See* Dr. Reddy Decl. ¶ 22; Dr. Genzen Decl. ¶ 27; Dr. Morice Decl. ¶¶ 12, 49, 52, 56–58, 62; Dr. Eisenberg Decl. ¶¶ 15–16; Dr. Fesko Decl. ¶ 15.

50. Under CLIA, all laboratories that perform clinical tests on human specimens must be certified by CMS or accredited through certain CMS-approved accreditation organizations. 42 U.S.C. § 263a(b); *see* Dr. Reddy Decl. ¶ 12; Dr. Genzen Decl. ¶ 15. Both CMS and accreditation organizations issue standards to assure that laboratories’ performance is “consistent” and their tests are “valid and reliable,” including quality-control standards and standards for the qualifications of the personnel directing, supervising, and performing the tests. 42 U.S.C. § 263a(f)(1). The standards must take into account, among other things, the type of tests performed, the “degree of independent judgment involved,” “the amount of interpretation involved,” “the difficulty of the calculations involved,” and “the type of training required.”

§ 263a(f)(2).

51. The College of American Pathologists is the most prominent example of a CMS-approved accreditation organization, and to be accredited by that organization, a laboratory must be inspected initially and then every two years and must demonstrate that it complies with approximately 3,000 specific requirements, including validation of any clinical claims made by the laboratory for any laboratory-developed testing service. *See* College of American Pathologists, *CAP Advances Quality in Laboratory Medicine and Safeguards Patient Testing with Annual Release of Laboratory Accreditation Program Checklists* (Sept. 23, 2021), <https://newsroom.cap.org/cap-in-the-news/cap-advances-quality-in-laboratory-medicine-and-safeguards-patient-testing-with-annual-release-of-la/s/88c2ad6c-72b4-4641-aaa7-3edb4954aac8>.

52. The CLIA regulations ensure that laboratory testing services are performed only by highly skilled and trained laboratory professionals. Laboratories that perform high-complexity tests must be overseen by a laboratory director, who must either be a licensed physician or hold a doctoral degree in a chemical, physical, biological, or clinical laboratory science. 42 C.F.R. § 493.1443. The laboratory director is responsible for ensuring that the laboratory's test methodologies are "capab[le] of providing the quality of results required for patient care," that "[l]aboratory personnel are performing the test methods as required for accurate and reliable results," and that "consultation

is available to the laboratory's clients on matters relating to the quality of the test results reported and their interpretation concerning specific patient conditions." *Id.* § 493.1407(e)(3), (9).

53. The laboratory must also have a technical supervisor with appropriate training or experience for the types of tests performed by the laboratory, *id.* § 493.1449, and a clinical consultant qualified to "consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment, and management of patient care," *id.* § 493.1455. The clinical consultant is responsible for providing "consultation regarding the appropriateness of the testing ordered and interpretation of test results." *Id.* § 493.1457. And all laboratory personnel who perform high-complexity tests must either be licensed physicians or have appropriate training and experience in laboratory science or medical technology. *Id.* § 493.1489.

54. Under CLIA, laboratory testing services are subject to strict quality controls. When a laboratory introduces a new diagnostic test "not subject to FDA clearance or approval" (or when it modifies an FDA-cleared or approved IVD test kit purchased from a device manufacturer), it must, "before reporting patient test results," establish "performance specifications" for the test—including specifications for accuracy, precision, analytical sensitivity, and other characteristics "required for test performance." *Id.* § 493.1253(b)(2). Performance of the test is also subject to the laboratory's CLIA-mandated

quality control system, which requires, among other things, establishment and performance of calibration and control procedures; maintenance and function checks for equipment, instruments and test systems; and ongoing quality monitoring. *Id.* § 493.1200–1299.

55. CLIA further requires laboratories to demonstrate proficiency in their tests multiple times a year. 42 U.S.C. § 263a(f)(3). For many of their tests, laboratories must enroll and participate in approved proficiency testing programs, which serve as external quality control checks for every test the laboratory performs. Proficiency testing requires that the laboratory test blinded samples according to its typical procedures and report the results back to the testing program for evaluation. 42 C.F.R. § 493.801. A laboratory that fails to achieve satisfactory proficiency scores may face sanctions, including suspension, limitation, or revocation of its CLIA certificate. *Id.* §§ 493.803(b), 493.1806.

56. CLIA-certified laboratories are subject to inspections, by the Department of Health and Human Services, state agencies, and authorized accrediting bodies. *See, e.g.*, 42 U.S.C. § 263a(g); 42 C.F.R. Part 493, Subpart Q.

57. Although CLIA was enacted nine years before the Medical Device Amendments and significantly expanded twelve years after those Amendments, neither CLIA nor its legislative history acknowledges any

authority of FDA to regulate laboratory testing services as medical devices.

58. The Senate Report on the 1967 bill addressed concerns about possible overlap between regulation of clinical laboratories under CLIA and under the Medicare statute, but it did not mention any role for FDA. *See* S. Rep. No. 90-724 (1967), *reprinted in* 1967 U.S.C.C.A.N. 2076, 2084.

59. Likewise, the House Report on the 1988 bill described “[t]he Current Regulatory System” as involving federal regulation of laboratories “under two programs”—the Clinical Laboratory Improvement Act of 1967 and the Medicare statute—and did not so much as mention regulation by FDA. H.R. Rep. No. 100-899, at 11 (1988). The Report also states that the purpose of CLIA was to replace a “confusing” system where laboratories were regulated under “two separate and distinct statutes” with a single “unified regulatory mechanism”—a purpose that is at odds with subjecting laboratory testing services to regulation under both CLIA and the FDCA. *Id.* at 12.

60. In short, there is no indication that Congress, when it enacted CLIA, believed that clinical laboratories’ provision of testing services was already subject to regulation under the FDCA.

D. FDA has never broadly regulated laboratory testing services as medical devices.

61. In the nearly half-century since Congress enacted the Medical Device Amendments of 1976—not to mention the 86 years since Congress first

gave FDA authority over medical devices in 1938—FDA has never before acted to broadly regulate laboratory-developed tests as “devices” under the FDCA. This lengthy history confirms that FDA lacks statutory authority to do so now. *See Util. Air Regul. Grp.*, 573 U.S. at 324 (an agency’s reliance on “a long-extant statute” to bring about a dramatic “expansion in [its] regulatory authority” should be met with “skepticism”); *Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 157–58 (2012) (when an agency has responded to an industry’s “decades-long practice” with a “lengthy period of conspicuous inaction,” the likely explanation is that the industry practice was lawful).

1. FDA’s Many Years of Silence

62. In the first 16 years following Congress’s enactment of the Medical Device Amendments to the FDCA, from 1976 through 1992, FDA did not claim any authority to regulate laboratory testing services as “devices.” Nor had FDA ever claimed such authority under the FDCA as enacted in 1938, even though that statute contained a similar definition of “device.”

63. Clinical laboratories thus reasonably understood that their services were not subject to regulation under the FDCA. *See* Dr. Reddy Decl. ¶ 24; Dr. Eisenberg Decl. ¶¶ 15–17; Dr. Fesko Decl. ¶ 14; Dr. Genzen Decl. ¶ 46. Congress acted on the same understanding when it enacted CLIA to create a single, unified, comprehensive system for the federal regulation of laboratory testing.

64. The first time FDA suggested that it might possess authority to regulate laboratory-developed tests as devices was in 1992—16 years after Congress enacted the Medical Device Amendments and 54 years after it first enacted the FDCA. But when that suggestion drew immediate and strenuous objections, FDA essentially backed down and announced a “policy” of not exercising jurisdiction over laboratory testing services that it adhered to for the next 30 years.

65. In its final rule, FDA cites a 1973 rulemaking as purported evidence that FDA treated tests as devices before Congress enacted the Medical Device Amendments. 89 Fed. Reg. 37,286, 37,328 (May 6, 2024) (citing 38 Fed. Reg. 7096 (Mar. 15, 1973)). That rulemaking defined “[i]n vitro diagnostic *products*”—not services—as diagnostic “reagents, instruments and systems.” 38 Fed. Reg. at 7098. (emphasis added). Although FDA now suggests that the term “systems” was intended to include testing services, the context makes clear that the only “systems” subject to the rule were finished products, not laboratory tests. For example, the 1973 rule included labeling provisions requiring that certain information be affixed to the “retail package” of the “article.” 38 Fed. Reg. at 7098. The 1973 rule thus confirms that FDA originally sought to regulate only physical products, not professional laboratory procedures or techniques. Moreover, when Congress amended the definition of “device” in 1976, it did not include the term “system” or even the term “in vitro

product,” but only the narrower term “in vitro reagent.”

2. FDA’s Never-Finalized 1992 Guidance

66. Sixteen years following the enactment of the Medical Device Amendments, in 1992, in a draft Compliance Policy Guide, FDA made the novel claim that it could regulate laboratory-developed tests as medical devices. This claim was made in passing in a document that generally addressed the marketing and distribution of IVD test kits. In a brief aside, FDA stated that “laboratories have been manufacturing ‘home brew’ products, either from products already on the market, or from components, and utilizing these unapproved products for diagnostic purposes,” and added that “[t]hese products are subject to the same regulatory requirements as any unapproved medical device.” FDA, Draft Compliance Policy Guide: Commercialization of Unapproved *In Vitro* Diagnostic Devices Labeled for Research and Investigation at 4 (Aug. 3, 1992).

67. The laboratory profession immediately objected to this abrupt and unexplained assertion of jurisdiction over professional laboratory testing services. For example, a law firm that represented clinical laboratories filed a citizen petition asking FDA not to assert jurisdiction over laboratories’ “in-house assays” and noting, among other concerns, that FDA’s authority over medical devices “does not extend to test methods, protocols, or services.” Citizen Pet. at 9, Hyman, Phelps & McNamara, P.C., Docket No. FDA-92-P-

0405 (Oct. 22, 1992) (“1992 Citizen Petition”).

68. FDA did not immediately respond to the 1992 Citizen Petition. But following controversy over the 1992 draft guidance, FDA did not finalize that guidance or attempt to actively regulate laboratory testing services. Instead, FDA sought to calm the waters by announcing that it did “not intend to routinely exercise its authority over home-brew tests.” *IVD Policy Will Not Include Exemptions for “Standard-of-Care” Tests*, THE GRAY SHEET (Oct. 11, 1993).

3. FDA’s Sporadic Claims of Authority in the 1990s and 2000s

69. FDA next asserted that it had jurisdiction over laboratory testing services in the non-binding preamble to a 1996 proposed rule regarding device classification levels for certain “active ingredients used in preparing in-house developed [laboratory] tests.” 61 Fed. Reg. 10,484, 10,485 (Mar. 14, 1996). In the preamble, FDA noted that it had previously regulated as devices only (i) “diagnostic tests that are traditionally manufactured and commercially marketed as finished products” (*i.e.*, test kits), and (ii) tangible articles used as test “ingredients,” such as “laboratory apparatus” and “chemicals or antibodies,” that laboratories “purchase from biological or chemical suppliers.” *Id.* at 10,484.

70. In response, ACLA and other stakeholders filed comments

challenging FDA's assumption that it had authority to regulate laboratory testing services as medical devices.

71. In the preamble to the final rule, FDA stated that it “believes that clinical laboratories that develop such [in-house] tests are acting as manufacturers of medical devices.” 62 Fed. Reg. at 62,249. FDA recognized, however, that “the use of in-house developed tests has contributed to enhanced standards of medical care in many circumstances and that significant regulatory changes to this area could have negative effects on the public health.” *Id.* FDA therefore stated that it would continue to focus on regulating “ingredients ... that move in commerce” and other tangible articles, not laboratory testing services. *Id.*; *see id.* at 62,250 (concluding that “regulation of all in-house developed tests” was not “appropriate at this time”).

72. Over the next 12 years, FDA continued to assert periodically and in draft non-binding guidance that it had statutory authority to regulate professional laboratory testing services as manufactured devices but was choosing not to. But FDA never took any final regulatory action backing up its non-binding statements. And the agency's consistent policy of *not* treating laboratory-developed tests as devices made these occasional claims nothing but empty posturing.

4. FDA's Never-Finalized 2014 Guidance

73. FDA's first real suggestion that it might put its posturing into

practice came in 2010, when the agency announced its intention to “reconsider its policy of enforcement discretion” with respect to laboratory-developed tests. 75 Fed. Reg. 34,463–64 (June 17, 2010). FDA said it intended to “develop a draft oversight framework for public comment” that would “phase in ... over time based on the level of risk” presented by various tests. *Id.*

74. In response, ACLA submitted comments reiterating that “laboratories are providers of testing services; they are not medical device manufacturers.” ACLA Supp. Comments on Oversight of Lab’y Developed Tests at 4, Docket No. FDA-2010-N-0274 (Sept. 15, 2010). ACLA explained that, while it might be appropriate for FDA to regulate as devices “the *products* used by clinical laboratories to perform tests,” including “commercially distributed *in vitro* diagnostic test kits,” FDA should not and cannot recklessly impose device regulation on the provision of “laboratory *services*.” *Id.* at 4, 6 (emphases added).

75. Two years later, with FDA still not having published any proposed oversight framework, Congress prohibited the agency from issuing “any draft or final guidance on the regulation of laboratory-developed tests” for five years unless the details of FDA’s plan were disclosed to the relevant congressional committees at least 60 days prior to such issuance. Pub. L. No. 112-144, § 1143(a), 126 Stat. 993, 1130 (2012).

76. A year after that, ACLA submitted a citizen petition asking FDA

to acknowledge that laboratory testing services are not devices. ACLA's petition explained that text and legislative history make clear that "devices" are tangible articles and do not include services or procedures. *See* ACLA Citizen Pet. at 7–9, Docket No. FDA-2013-P-0667 (June 4, 2013). The petition acknowledged that performing a laboratory-developed test "might involve use of" physical devices, such as "reagents," "laboratory equipment," or "IVD test kits." *Id.* at 1, 8. But it stressed that a clinical service does not become subject to regulation as a device "simply because the service involves the use of tangible articles which may be subject to FDA regulation." *Id.* at 8–9. Otherwise, it noted, "every surgical procedure or physical examination that is performed on a patient using tangible devices" would itself be a "device." *Id.*

77. FDA denied ACLA's citizen petition in 2014 and asserted that laboratory-developed tests "are 'devices' as defined in the FDCA." FDA Denial of ACLA Citizen Pet. at 3, Docket No. FDA-2013-P-0667 (July 31, 2014). Eliding the distinction between professional services and physical products, FDA claimed that laboratory testing services are devices because they *make use of* various physical "articles," such as "reagents," "instruments," and "equipment"—even though the testing services themselves are plainly not "articles." *Id.* at 3–5, 23.

78. On the same day it denied ACLA's citizen petition, FDA made similar assertions in response to two other citizen petitions, which had been

pending since 2006 and 2008, respectively. *See* FDA Denial of Wash. Legal Found. Citizen Pet. at 3–4, Docket No. FDA-2006-P-0149 (July 31, 2014); FDA Denial of Genentech, Inc., Citizen Pet. at 5–6, Docket No. FDA-2008-P-0638 (July 31, 2014). Also on that day, FDA notified Congress of its intent to issue draft guidance documents regarding laboratory-developed tests.

79. On October 3, 2014, FDA released the draft guidance documents it had promised in 2010, proposing to phase in new regulation of laboratory-developed tests as devices over a nine-year period. In announcing the draft guidance documents, FDA described laboratory-developed tests as “a subset of in vitro diagnostic devices that are intended for clinical use and designed, manufactured, and used within a single laboratory.” 79 Fed. Reg. 59,776, 59,777 (Oct. 3, 2014); *see also* 79 Fed. Reg. 59,779, 59,780 (Oct. 3, 2014).

80. ACLA submitted comments on the draft guidance documents. Among other points, ACLA’s comments explained once again that “a ‘device’ is a physical article or product” and “[l]aboratory-developed testing services are processes and methodologies that are qualitatively and categorically different from the tangible goods that FDA may regulate as ‘devices.’” ACLA Comments on Oversight of Laboratory Developed Tests and Reporting at 5, Docket Nos. FDA-2011-D-0357 & -0360 (Feb. 2, 2015). ACLA also reiterated that “[l]aboratory-developed testing services do not become medical devices merely because they sometimes utilize other medical devices,” such as reagents and

laboratory equipment. *Id.* at 6. As ACLA noted, “every time a radiologist reads an x-ray, she is providing a service that depends on a medical device—the x-ray machine. However, the radiologist is rendering a service and is not subject to regulation under the FDCA” as a device manufacturer. *Id.*

81. On November 18, 2016, FDA backed down, announcing that it would not finalize the 2014 draft guidance documents. In a white paper published in January 2017, FDA noted that it had made this decision “to allow for further public discussion on an appropriate oversight approach, and to give our congressional authorizing committees the opportunity to develop a legislative solution.” FDA, Discussion Paper on Laboratory Developed Tests (LDTs) at 1 (Jan. 13, 2017).

5. The 2020 Charrow Memo Questions FDA’s Authority to Regulate Laboratory Testing Services

82. In 2020, Robert Charrow, then-General Counsel of the Department of Health and Human Services, issued a memorandum regarding “Federal Authority to Regulate Laboratory Developed Tests.”

83. The Charrow memorandum is significant because it addresses and undermines key premises upon which FDA now relies. For example, it recognized that laboratory-developed tests “were never mentioned in the [Medical Device Amendments], in the House Report accompanying it, or during the floor debates.” Mem. from Robert Charrow, Gen. Counsel, to Stephen

Hahn, M.D., Comm’r of Food & Drugs, at 3 (June 22, 2020) (attached as Ex. F). It further noted that Congress’s enactment of CLIA in 1988, and the Secretary’s issuance of “comprehensive rules governing clinical laboratories” pursuant to CLIA, “appeared to have occupied the field for regulating [laboratory-developed tests].” *Id.* at 3–4.

84. Contrary to FDA’s claims that it regarded laboratory-developed tests to be devices as far back as 1976, the Charrow memorandum acknowledges that FDA had “first suggested that [laboratory-developed tests] are subject to its jurisdiction” in 1992—16 years after the Medical Device Amendments were enacted—and that from 1992 until 2014, “FDA did little to regulate LDTs.” *Id.* at 4. Moreover, although FDA had proposed altering that status quo in 2014 when it published the draft guidance documents, it had subsequently declined to finalize those documents. *Id.* at 5.

85. Acknowledging the argument that laboratory-developed tests “are not physical embodiments, *e.g.* ‘contraptions,’ but rather are processes or services, and therefore not devices,” the Charrow memorandum observed that while “*in vitro* reagents are devices, ... that does not necessarily lead to the conclusion that [laboratory-developed tests] fall within FDA’s jurisdiction.” *Id.* at 6. The memorandum explained that Congress’s enactments do not “lead[] to the conclusion that [laboratory-developed tests] are devices” and “the Secretary has issued rules implementing Medicare and CLIA that strongly

suggest that [laboratory-developed tests] are not devices and not within FDA’s jurisdiction.” *Id.* at 14.

86. The memorandum also recognized that laboratory-developed tests are not “goods or commodities” but rather “clinical laboratory services,” and are treated as such by Medicare. *Id.* at 10. The memorandum analogized “the development and use of” laboratory-developed tests to a “doctor’s development and use of a medical procedure.” *Id.*

6. Congress Chooses Not to Enact Legislation

87. Reflecting the lack of statutory authority for FDA to regulate laboratory testing services under the FDCA, Congress considered legislative proposals that would have given FDA such authority. On March 5, 2020, the VALID Act was introduced in both houses of Congress. *See* Verifying Accurate Leading-edge IVCT Development Act of 2020, H.R. 6102, 116th Cong. (2020) (companion bill S.3404). The Act would have created a new regulatory pathway, separate from both drugs and devices, for FDA premarket review and regulation of “in vitro clinical tests,” including laboratory-developed tests. *See id.* § 2(a).

88. Commentators noted that “[e]arlier versions of the proposed VALID Act had been circulating in Washington for several years” following FDA’s “abortive” attempt to regulate laboratory-developed tests in 2014, which FDA had “abandoned” in 2016 “amid questions about [its] jurisdiction to

regulate laboratory services.” Barbara J. Evans & Ellen Wright Clayton, *Deadly Delay: The FDA’s Role in America’s COVID-Testing Debacle*, 130 Yale L.J. Forum 78, 83–84 (2020)).

89. The VALID Act did not pass during the 116th Congress. It was reintroduced in the 117th Congress, where it again failed to pass. *See* VALID Act of 2021, H.R. 4128, 117th Cong. (2021) (companion bill S.2209). It was introduced again in 118th Congress, and once again it failed to become law. *See* VALID Act of 2023, H.R. 2369, 118th Cong. (2023) (companion bill S.2496).

E. FDA now seeks for the first time to classify virtually all laboratory testing services as medical devices.

1. The 2023 Proposed Rule

90. With no congressional authorization forthcoming, FDA once again announced its intent to move forward with regulating virtually all laboratory-developed testing services as medical devices. FDA published its proposed rule in October 2023. *See* 88 Fed. Reg. 68,006 (Oct. 3, 2023).

91. In the proposed rule, FDA stated that it would amend a regulatory definition of “in vitro diagnostic products” to add the underlined language:

[In vitro diagnostic products] are defined as “those reagents, instruments, and systems intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae. Such products are intended for use in the collection, preparation, and examination of specimens taken from the human body.” ... These products are

devices as defined in section 201(h)(1) of the Federal Food, Drug, and Cosmetic Act (the act) and may also be biological products subject to section 351 of the Public Health Service Act, including when the manufacturer of these products is a laboratory.

See id. at 68,017, 68,031 (proposed amendment to 21 C.F.R. § 809.3(a)). In the preamble, FDA made clear that it intended this amendment to signify that all laboratory testing services are “devices” and that whenever a laboratory scientist or technician performs a clinical laboratory test, he or she is engaged in “manufacturing” a “device.” *Id.* at 68,007–09, 68,017–19.

92. In the preamble to the proposed rule, FDA also stated its intent to “phase out its general enforcement discretion approach” so that most laboratory-developed tests would “fall under the same enforcement approach as other” medical devices within a few years. *Id.* at 68,007.

93. FDA also recognized that its rule would impose vast costs on the clinical laboratory sector (although again, its projections were low). It estimated that the up-front cost of preparing and submitting premarket approval applications, premarket notifications, and de novo classification requests *for existing tests alone* would exceed \$35 billion and could be as high as \$113 billion. FDA, Docket No. FDA-2023-N-2177, Laboratory Developed Tests Proposed Rule: Preliminary Regulatory Impact Analysis at 85 (Oct. 3, 2023). It also estimated that going forward, the annual compliance for affected laboratories would be more than \$4 billion and could be as high as \$14 billion.

Id.; see also Dr. Genzen Decl. ¶¶ 54–60 (explaining why FDA’s analysis “overestimates the financial benefit to society” and “understates the costs”).

94. FDA acknowledged that these costs would cause some existing tests to “come off the market” because laboratories would not be able to justify the high costs of obtaining the necessary approval or clearance for those tests. 88 Fed. Reg. at 68,014.

2. ACLA’s Comments on the Proposed Rule

95. FDA received more than 6,000 comments on its proposed rule, a volume of public input that reflects the radical and transformative nature of FDA’s proposal.

96. ACLA submitted its comments on December 4, 2023. Among other critical points, ACLA’s comments explained, yet again, that FDA does not have legal authority to regulate laboratory-developed tests as devices—including because “devices” under the FDCA are physical products that are sold and distributed by manufacturers, whereas laboratory-developed tests are services offered by trained laboratory professionals that are regulated under CLIA’s distinct statutory and regulatory framework. See ACLA Comments on Proposed Rule “Medical Devices; Laboratory Developed Tests” at 59–71, Docket No. FDA-2023-N-2177 (Dec. 4, 2023) (attached as Ex. G). ACLA’s comments also explained that FDA’s unlawful assertion of jurisdiction over clinical laboratory services would seriously harm patients by undermining

diagnostic and medical innovation and limiting or eliminating access to critical tests. *Id.* at 7–18.

97. In addition, ACLA’s comments demonstrated that FDA had vastly underestimated the costs of regulating laboratory-developed tests as devices—including by underestimating the number of affected laboratories, the number of currently available tests that would require costly and time-consuming premarket submissions, the cost of preparing those submissions, and the cost of complying with other device regulations. *Id.* at 46–54. And conversely, ACLA showed that FDA had vastly *overestimated* the benefits of its novel regulatory approach, including by using cherry-picked, anecdotal, and unverified “evidence” to paint an unfairly disparaging picture of laboratory testing services, while ignoring studies showing that laboratory-developed tests perform at least as well as FDA-approved or cleared IVD test kits. *Id.* at 36–46, 54–59.

3. The 2024 Final Rule

98. FDA published the final rule on May 6, 2024.

99. As contemplated in the proposed rule, FDA amended the regulatory definition of “in vitro diagnostic products” in 21 C.F.R. § 809.3(a) to add the language, “including when the manufacturer of these products is a laboratory.” 89 Fed. Reg. at 37,286–87. And, as in the proposed rule, FDA made clear that it considers the provision of laboratory-based testing services a form

of device “manufacturing.” *See id.* at 37,286–87, 37,289, 37,293, 37,328–32, 37,344.

100. In a major departure from the proposed rule, however, the preamble to the final rule states that FDA intends—for now and until it changes its mind—to exercise “enforcement discretion” for some or all requirements with respect to broad categories of laboratory-developed tests, including nearly all existing tests. *Id.* at 37,294–95. These non-binding “enforcement discretion policies” include the following:

- FDA will generally not enforce premarket review and Quality System (“QS”) requirements for existing tests that are not modified or that are “modified in certain limited ways.”
- FDA will generally not enforce premarket review requirements for tests approved by the New York State Department of Health’s Clinical Laboratory Evaluation Program.
- FDA will generally not enforce premarket review and QS requirements (except certain recordkeeping requirements) for tests “manufactured and performed” by a laboratory integrated within a healthcare system to meet an unmet need of patients receiving care within the same healthcare system.
- FDA will generally not enforce premarket review and QS requirements (except certain recordkeeping requirements) for non-molecular antisera tests for rare red blood cell antigens where such tests are “manufactured and performed” in blood establishments, including transfusion services and immunohematology laboratories, and where there is no alternative available to meet the patient’s need for a compatible blood transfusion.
- FDA will generally not enforce any requirements for “1976-Type LDTs” (tests with certain characteristics that FDA says were common among laboratory-developed tests offered in 1976).

- FDA will generally not enforce any requirements for Human Leukocyte Antigen tests that meet certain specified characteristics.
- FDA will generally not enforce any requirements for tests intended solely for forensic (law enforcement) purposes.
- FDA will generally not enforce any requirements for tests “manufactured and performed” within the Department of Defense or the Veterans Health Administration.

Id.

101. These extensive carveouts are necessary, the final rule acknowledges, because “expecting compliance with full [quality system] and premarket review requirements for all currently marketed” laboratory-developed tests “could lead to the loss of access to safe and effective” tests “on which patients currently rely.” *Id.* at 37,293; *see* Dr. Reddy. Decl. ¶ 6; Dr. Genzen Decl. ¶¶ 47, 56; Dr. Morice Decl. ¶¶ 15–16, 59–65.

102. In other words, faced with the impracticality and catastrophic impact of its novel interpretation of the law, FDA did not take that unworkability as a hint that its interpretation might be mistaken. Instead, to try to contain the damage, FDA effectively used a non-binding regulatory preamble to write a new statute on the fly, under the guise of “enforcement discretion policies.”

103. These broad carveouts undermine FDA’s legal rationale for the rule, which classifies all laboratory-developed tests as manufactured “devices” subject to the full suite of medical-device requirements regardless of whether

the tests fall into the categories outlined in the enforcement discretion policies. For example, FDA does not identify any textual basis in the statute for subjecting new tests to a different regime than existing tests.

104. The broad carveouts are also inconsistent with FDA’s public-health rationale for the rule. For example, FDA cannot explain why, on the one hand, more limited regulation is sufficient for the tens of thousands of laboratory-developed tests in existence at the time of the final rule, but on the other hand, virtually every test developed *after* May 6, 2024, must run the full gauntlet of the medical-device requirements.

105. The final rule states that FDA will phase out its “general enforcement discretion approach” within a four-year period. 89 Fed. Reg. at 37,294. As a result, excepting the “enforcement discretion policies” described above, FDA will begin enforcing medical-device requirements with respect to laboratory-developed tests in five stages measured from the date of publication of the final rule:

- ***After 1 year***, FDA will expect compliance with medical device reporting (“MDR”) requirements, correction and removal reporting requirements, and some QS requirements under 21 C.F.R. § 820.198.
- ***After 2 years***, FDA will expect compliance with requirements not covered during other stages of the phaseout policy, including registration and listing requirements, labeling requirements, and investigational use requirements.
- ***After 3 years***, FDA will expect compliance with other QS requirements under 21 C.F.R. § 820.198.

- ***After 3½ years***, FDA will expect compliance with premarket review requirements for “high-risk IVDs offered as LDTs.”
- ***After 4 years***, FDA will expect compliance with premarket review requirements for “moderate-risk and low-risk IVDs offered as LDTs.”

Id.

106. At the same time, the final rule emphasizes that both the “enforcement discretion policies” and the phased-in approach are merely matters of prosecutorial discretion and that laboratories are legally required to comply with *all* medical-device regulations *immediately*. The rule states that “the phaseout policy does not in any way alter the fact that it is illegal to offer” laboratory-developed tests “without complying with applicable requirements” and stresses that “[r]egardless of the phaseout timeline and enforcement discretion policies ... FDA retains discretion to pursue enforcement action for violations of the FD&C Act at any time, and intends to do so when appropriate.” *Id.* at 37,295.

107. With respect to the “enforcement discretion policies,” FDA further cautions that “[a]s with any enforcement discretion policy, FDA may update any of these policies as circumstances warrant or if the circumstances that inform these policies change.” *Id.* at 37,297. FDA again emphasizes that “these enforcement discretion policies do not confer lawful marketing status on any [laboratory-developed tests] being marketed as described in the policies” and “do not in any way alter the fact that it is illegal to market [a laboratory-

developed test] that lacks required premarket authorization or is otherwise in violation” of federal law. *Id.*

108. The final rule also warns that FDA “intends to take action to enforce applicable requirements for [laboratory-developed tests] ... as appropriate, taking into account any public health concerns as evaluated on a case-by-case basis.” *Id.* For example, “if FDA receives reports, or otherwise learns of information, that raise safety or effectiveness concerns with [a laboratory-developed test] that falls within an enforcement discretion policy, FDA generally intends to take action with respect to requirements applicable to that specific [test].” *Id.*

109. Again and again throughout the final rule, FDA declares that no laboratory is safe from enforcement merely because its conduct is consistent with FDA’s stated enforcement discretion policies. *See id.* at 37,301 (“[A]s noted elsewhere in this preamble, regardless of this or any other enforcement discretion policy, FDA retains discretion to pursue enforcement action at any time against violative [laboratory-developed tests] when appropriate.”); *id.* at 37,304 (same); *id.* at 37,307 (same).

110. As to existing tests, the final rule also states that FDA will expect compliance with premarket review and quality system requirements whenever the test is “changed in certain, more significant ways that could affect its basic safety and effectiveness profile,” such as “includ[ing] significantly different

technology” in the test. *Id.* at 37,305. FDA does not explain how a laboratory might determine when a difference in technology is so “significant” as to trigger an expectation of compliance.

111. Under the final rule, FDA thus continues to assert comprehensive authority to regulate virtually all laboratory-developed tests as medical devices. FDA then tries to mitigate the fallout from that regulatory sea change by announcing vague, non-binding enforcement discretion policies in a 150-plus-page preamble to its final rule. But FDA takes the position that even laboratories acting within the scope of those vaguely defined policies are violating federal law and that FDA can decide to prosecute them at any time, leaving laboratories “at the mercy of [FDA’s] *noblesse oblige*.” *FCC v. Fox Television Stations, Inc.*, 567 U.S. 239, 255 (2012) (quoting *United States v. Stevens*, 559 U.S. 460, 480 (2010)).

112. In response to comments questioning FDA’s legal authority, FDA doubles down on its theory that professional laboratory testing services are medical “devices” just like pacemakers or test kits. “As an initial matter,” FDA says, “FDA does not read the definition of device to encompass only physical objects.” 89 Fed. Reg. at 37,331. And “[r]egardless” of that reading (*i.e.*, even assuming the “device” definition is limited to tangible products), FDA explains, “a test system” developed by a laboratory “is a physical product and a material thing” because it involves “a set of components—such as reagents,

instruments, and other articles—that function together to produce a test result.” *Id.* In other words, FDA’s position is that whenever laboratory professionals use multiple tangible articles together to perform a test, they are “manufacturing” a “device.” While FDA superficially disclaims that view, stating that its “position is not that laboratory services are articles but that in vitro diagnostic products used in laboratories (such as test systems) are articles,” FDA has effectively adopted a definition of “test systems” that conflates professional laboratory services with the articles used to perform those services.

113. Whereas the statutory definition of “device” refers to discrete objects or fixed assemblages of objects, which can typically be packaged and shipped, FDA’s approach treats as a “device” even a set of transient relationships between physical articles used by a skilled professional. For example, under FDA’s reductionist approach, if a surgeon uses multiple objects to perform a procedure, such as a scalpel and a set of sutures, the surgeon has “manufactured” a “device” by using those objects in combination.

114. In the final rule’s preamble, FDA also asserts that the statutory term “article” cannot be limited to tangible goods because, in FDA’s view, computer software can qualify as a medical device despite being “an intangible thing.” 89 Fed. Reg. at 37,331–32. Even assuming FDA is correct that software may sometimes qualify as a device, that does not support FDA’s assertion that

the “device” definition can be stretched to cover the intangible professional services provided by laboratory medical professionals, which are different from manufactured medical devices. As the Supreme Court has explained, while it is possible to conceive of “software in the abstract: the instructions themselves detached from any medium,” “[w]hat retailers sell, and consumers buy,” are “tangible,” “physical cop[ies] of the software” that, whether “delivered by CD-ROM” or “downloaded from the Internet,” are ultimately “contained in and continuously performed by” a piece of physical hardware such as a computer. *Microsoft Corp. v. AT&T Corp.*, 550 U.S. 437, 446–48, 449–51 (2007).

115. FDA acknowledges that the final rule will impose major burdens on laboratories, but as with the proposed rule, FDA underestimates the impact. FDA projects that the requirements in the final rule will initially affect about 79,114 existing tests offered by 1,181 existing laboratories, and that it will also affect about 10,013 new tests offered every year going forward. *See* FDA, Laboratory Developed Tests Final Rule: Final Regulatory Impact Analysis at 36, 54–55 (May 6, 2024) (“Final Impact Analysis”) (attached as Ex. H). As FDA notes, “most facilities that will be affected by this rule are defined as small businesses and the final rule is likely to impose a substantial burden on the affected small entities.” *Id.* at 6–7; 89 Fed. Reg. at 37,433.

116. Even under the generous assumption that FDA will adhere to its non-binding enforcement discretion policies, *see* Final Impact Analysis at 37–

38, FDA estimates that it will need to review an additional 103 premarket applications, 1,090 premarket notifications, and 267 de novo classification requests each year—a vast increase in each category compared to the average from 2017 to 2021, including more than a doubling of the number of premarket applications, *see id.* at 57.

117. FDA estimates that the compliance costs for laboratories will total well over \$1 billion per year. *See id.* at 2, 135, 178. Over the next two decades, FDA projects that total costs associated with the final rule will range from \$12.57 billion to \$78.99 billion, with a primary estimate of \$28.61 billion. *Id.* at 125.

118. FDA acknowledges that the huge “increased cost to laboratories” may cause price increases for customers and “reduce the amount of revenue a laboratory can invest in creating and/or modifying” tests. *Id.* at 127.

F. HealthTrackRX and other ACLA members face irreparable harm from FDA’s final rule.

119. Under Fifth Circuit precedent, “the nonrecoverable costs of complying with a putatively invalid regulation typically constitute irreparable harm.” *Rest. L. Ctr. v. U.S. Dep’t of Lab.*, 66 F.4th 593, 597 (5th Cir. 2023) (collecting cases).

120. By FDA’s own admission, the final rule will impose significant nonrecoverable compliance costs on regulated laboratories, including

HealthTrackRX and other ACLA members. *See* Final Impact Analysis at 125 (estimating compliance costs of about \$101 million in year 1, \$113 million in year 2, \$386 million in year 3, and more than \$1.6 billion every following year). These costs will be unrecoverable because FDA, like other federal agencies, enjoys sovereign immunity from monetary damages. *See Rest. L. Ctr.*, 66 F.4th at 598.

121. HealthTrackRX and other ACLA members will need to begin incurring these costs immediately. FDA has made clear that despite the “phaseout” timeline and “enforcement discretion” policies in the final rule, it “retains the authority to enforce any applicable requirements and pursue enforcement action *at any time*” against laboratories that offer laboratory-developed tests without complying with regulatory requirements applicable to medical devices. 89 Fed. Reg. at 37,372 (emphasis added). And even if FDA were to commit to not taking enforcement action before the dates set forth in the policy (and FDA has expressly disclaimed such a commitment), laboratories would still have to begin incurring compliance costs well in advance of those dates to ensure full compliance by the relevant deadline.

122. Although FDA greatly underestimates both the magnitude of unrecoverable compliance costs and how quickly laboratories will begin incurring those costs, even FDA suggests that laboratories’ costs of compliance in the first year after publication of the final rule will range from \$47.85 million

to \$216.75 million, with a primary estimate of \$101.46 million. *See* Final Impact Analysis at 125. Those unrecoverable costs alone are sufficient to establish that laboratories face irreparable harm from the final rule.

123. Moreover, FDA wrongly assumes that laboratories will be able to defer certain compliance costs for several years. For example, FDA predicts that costs associated with preparing and submitting premarket approval applications, premarket notifications, and de novo classification requests for laboratory-developed tests—costs that FDA acknowledges will easily run to billions of dollars—will not occur until the third year after publication of the final rule. *See id.* at 124–25.

124. Contrary to FDA’s assumptions, laboratories cannot delay incurring these costs until just six to eighteen months before FDA says it will begin enforcing premarket review requirements. Indeed, to support premarket applications, laboratories will need to begin preparatory work immediately, including meeting with FDA reviewers to agree on analytical and clinical validation study protocols, running such validation studies, and otherwise compiling the voluminous material required to support FDA approval or clearance.

125. HealthTrackRx and other ACLA members have made substantial financial investments to maintain and expand their business—including opening new laboratories, acquiring assets, and hiring employees—in reliance

on the understanding that laboratory testing services are not subject to FDA regulation as medical devices and are instead regulated under CLIA and applicable state law. Dr. Reddy Decl. ¶ 24; Dr. Eisenberg Decl. ¶ 18; Dr. Fesko Decl. ¶ 16; Dr. Genzen Decl. ¶ 22; Dr. Morice Decl. ¶ 66.

126. FDA's final rule puts HealthTrackRx and other ACLA members in an untenable situation of regulatory uncertainty, which creates a serious risk of chilling investment in the maintenance of existing testing services and the development of new or modified testing services. Dr. Reddy Decl. ¶ 27; Dr. Eisenberg Decl. ¶ 17; Dr. Fesko Decl. ¶¶ 18–21; Dr. Genzen Decl. ¶¶ 47, 52; Dr. Morice Decl. ¶¶ 15–16, 58–65, 68.

127. ACLA members have already expended substantial time and capital to prepare for, and ensure that they are able to comply with, FDA's final rule. *See* Dr. Reddy Decl. ¶ 26.

128. If FDA's final rule is permitted to take effect, ACLA members will face even greater unrecoverable costs, often in the hundreds of thousands of dollars or more per test, in order to ensure that they can remain in compliance with federal law. *See id.* ¶ 29; Dr. Fesko Decl. ¶ 19; Dr. Genzen Decl. ¶¶ 50, 56.

129. If the final rule is allowed to remain in place, there is a substantial risk that some tests will no longer be available to help providers and patients because of the prohibitive costs of seeking FDA approval and clearance, especially for tests that are not high-volume. *See* Dr. Reddy Decl. ¶ 31; Dr.

Genzen Decl. ¶¶ 56, 58; Dr. Morice Decl. ¶¶ 16, 59–61.

130. Given the unrecoverable costs of complying with the FDA’s medical device requirements, and the likelihood that device regulation will exacerbate an FDA-review bottleneck, the final rule will hinder innovation by making it more difficult for ACLA members to develop, and for patients to access, new and modified tests. *See* Dr. Reddy Decl. ¶¶ 32–37; Dr. Genzen Decl. ¶¶ 47–51; Dr. Morice Decl. ¶¶ 15–16, 59–65, 68; Dr. Fesko Decl. ¶ 21.

CLAIMS FOR RELIEF

COUNT 1

Violation of the Administrative Procedure Act—Contrary to Law, in Excess of Statutory Jurisdiction and Authority, and Contrary to Constitutional Right and Power 5 U.S.C. § 706(2)

131. Plaintiffs reallege and incorporate by reference each of the preceding paragraphs as if set forth fully herein.

132. Under the Administrative Procedure Act, a court must set aside agency action that is not in accordance with law or in excess of statutory authority. *See* 5 U.S.C. § 706. An agency action is invalid and must be vacated if it exceeds the power conferred upon the agency by the statute. *See Perez v. Mortg. Bankers Ass’n*, 575 U.S. 92, 104–05 (2015).

133. FDA’s final rule is contrary to law and in excess of FDA’s statutory jurisdiction and authority because it treats laboratory testing services as medical devices that are subject to regulation under the FDCA, when in fact

they are services performed by highly skilled healthcare professionals.

134. The text, structure, and history of the FDCA make clear that a device is a physical product, not a professional service. Treating laboratory testing services as devices would not only do violence to the statutory definition of “device,” but would also require distorting numerous other statutory and regulatory provisions that confirm that FDA’s device authority is limited to physical goods.

135. The text and history of CLIA provide further confirmation that laboratory services are not devices subject to regulation under the FDCA. In CLIA, Congress created a comprehensive framework for the regulation of professional laboratory testing services—including extensive personnel qualification requirements, quality controls, and proficiency testing—that is separate and distinct from the framework for regulation of manufactured medical devices under the FDCA. Congress first enacted CLIA in 1967, nine years before the Medical Device Amendments, and significantly expanded CLIA in 1988, twelve years after those Amendments. In doing so, Congress never so much as hinted at any existing authority of FDA to regulate laboratory testing services under the FDCA. And when Congress acted to create a distinct and uniform system of regulation for clinical laboratories, it clearly indicated that FDA had no such authority.

136. Although the clarity of the statutory text should put an end to the

inquiry, FDA's attempt to regulate laboratory testing services as devices also implicates the major questions doctrine. *See West Virginia*, 597 U.S. at 724. FDA's rule would mean that the entire clinical laboratory sector, which is a significant part of the U.S. healthcare system, has been breaking the law for nearly 50 years, and possibly much longer. And it would mean that going forward, the entire profession is operating unlawfully and can be subject to civil and criminal penalties at any time, with its only protection coming from a policy of enforcement discretion that FDA insists it is free to revoke at any time. The rule would also wreak havoc on clinical laboratories and the doctors and patients they serve, imposing billions of dollars in immediate, unnecessary costs and preventing countless new tests from ever being developed. And it would produce a vast increase in the number of medical-device applications FDA must review every year.

137. An agency cannot impose massive costs and place an entire profession under its thumb in this manner without, at minimum, a clear statement from Congress. The Supreme Court has repeatedly warned that agencies should not attempt, and courts should not abide, such drastic expansions of the agency's authority under a "long-extant statute"—especially where, as here, Congress has "conspicuously and repeatedly declined to enact" such an expansion itself. *West Virginia*, 597 U.S. at 724 (quoting *Util. Air Regul. Grp.*, 573 U.S. at 324).

COUNT 2
Violation of the Administrative Procedure Act—
Arbitrary and Capricious and an Abuse of Discretion
5 U.S.C. § 706(2)

138. Plaintiffs reallege and incorporate by reference each of the preceding paragraphs as if set forth fully herein.

139. Under the Administrative Procedure Act, a court must set aside agency action that is arbitrary and capricious, an abuse of discretion, or inconsistent with the requirements of reasoned decision-making. *See* 5 U.S.C. § 706. An action is arbitrary and capricious if agency acts outside the reasonable scope of its lawful authority, fails to articulate a satisfactory explanation for its actions, or fails to respond adequately and reasonably to comments and objections.

140. FDA has not acted consistent with the requirements of reasoned decision-making because it has not adequately responded to objections, provided a reasoned justification for its rule, or reasonably explained its sweeping assertion of new regulatory authority. FDA's decision to exercise enforcement discretion through the use of non-binding guidance in a preamble only underscores how unreasonable it is for FDA to outlaw an entire sector of professional services, especially given the reliance interests at stake.

141. Accordingly, even if Congress had granted FDA authority under the FDCA to regulate certain types of laboratory-developed tests as medical

devices, the agency has not exercised that authority consistent with the requirements of reasoned decision-making under the Administrative Procedure Act and the Constitution's separation of powers.

142. FDA's final rule cannot be allowed to stand because it is ultra vires, arbitrary and capricious, and an abuse of discretion.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request that the Court:

A. Enter a declaratory judgment that FDA's final rule is contrary to law; in excess of statutory jurisdiction, authority, or limitations; and arbitrary or capricious, and that FDA is not authorized to regulate laboratory testing services as medical devices under the FDCA.

B. Enter an order that vacates FDA's final rule and enjoins FDA from enforcing the final rule and regulating laboratory testing services as medical devices under the FDCA.

C. Order such other and further relief as the Court deems just and proper.

Dated: May 29, 2024

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Respectfully submitted,

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